

## **II. REMARKS**

Claims 1 to 30 pending in the subject application, which were incorrectly noted on the Office Action Summary Transmittal. Claims 2, 4-11 and 14-30 have been withdrawn from consideration as a result of a requirement for restriction. Claims 1, 3, 12 and 13 stand variously rejected by the Office. Claims 1, 12 and 13 have been amended to specifically recite the species elected by Applicants. Claim 3 has been canceled without prejudice or disclaimer. An issue of new matter is not raised by these amendments and entry thereof is respectfully requested.

The amendments to the claims have been made in a sincere effort to remove the grounds for objection and rejection and are not intended to be a dedication to the public of the subject matter of the claims as originally presented.

In view of the preceding amendments and remarks that follow, reconsideration and withdrawal of the objections and rejections set forth in the October 20, 2004 Office Action are respectfully requested.

### **Oath and Declaration**

The Office objected to the Oath and Declaration and requested a Substitute Oath and Declaration. A new Substitute Oath and Declaration in compliance with 37 C.F.R. .1.67(a) will be provided as soon as possible.

### **Specification**

The Office objected to the specification for the improper indication of trademarked products. The specification has been amended to comply with MPEP § 608.01(v). (*See* Amendments Specification on page 2 of this paper.) In view of these amendments, reconsideration and withdrawal of the objection to the specification is respectfully requested.

### **Claim Objections**

The Office objected to claims 1, 12 and 13 for allegedly being drawn to the subject matter of non-elected (i.e., withdrawn) inventions. (*See* page 6 of Office Action). In response to the objection, claims 1, 12, and 13 have been amended. In view of these amendments, Applicants respectfully request withdrawal of this objection.

The Office also objected to the misspelling of the word “presence” in claim 12. (See page 6 of Office Action.) In response Claim 12 has been amended to correctly spell “presence.” Applicants therefore respectfully request withdrawal of this objection.

### **35 U.S.C. § 112 Second Paragraph**

The Office rejected claim 13 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More particularly, the Office alleged that claim 13 was indefinite because term, “the lung cancer,” had no antecedent basis.

Claim 13 has been amended by deleting “lung cancer” and by adding “neoplastic condition of a lung cell,” which has antecedent basis from claim 1. Support for this amendment is found in the specification on page 3, lines 5-14 in the substitute specification. In view of this amendment, reconsideration and withdrawal of the rejection is respectfully requested.

### **35 U.S.C. § 102(b)**

The Office rejected claims 1, 3, 12 and 13 under 35 U.S.C. § 102(b) as allegedly anticipated by Mooi *et al.* (Histopathology (1988) Sep; 13(3): 329-337). The Office stated that, “Mooi et al. teaches a method for aiding in the diagnosis of primary lung carcinomas, including, in particular, non-small cell lung cancer, comprising detecting the presence of the protein gene product 9.5 (PGP9.5) in lung cell samples.” However, the Office admitted that “Mooi et al. does not explicitly teach the gene encoding PGP9.5 is ‘overexpressed’ or that its overexpression is indicative of cancer.” (See page 7 of Office Action mailed October 20, 2004.)

Applicants respectfully traverse. Claim 3 has been canceled without prejudice or disclaimer. Claims 1, 12 and 13 are directed to a method for aiding in the diagnosis of a neoplastic condition of a lung cell by detecting the presence of an overexposed proto-oncogene PGP9.5 in a sample of lung tissue. The method can be practiced by detecting the amount of polypeptide or protein encoded by the proto-oncogene. The method can be used to detect non-small cell lung cancer.

MPEP 706.02 section IV notes that “for anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present.” As admitted by the Office, Mooi *et al.* does not


teach the element of “an overexpressed proto-oncogene” or that its “overexpression is indicative of cancer.” Further, the reference does not impliedly teach this element nor is “overexpression” inherently present in the Mooi *et al.* reference. The Office also cited Wilkinson *et al.* (Science (1989) Nov 3; 246 (4930):670-673) as evidence that the PGP9.5 gene is normally only expressed in select neurons and ganglia. Applicants submit that the combination of Wilkinson *et al.* with Mooi *et al.* is inappropriate for a rejection based on 35 U.S.C. § 102(b), which requires that all elements of the claim be taught by the one reference. Neither Wilkinson *et al.* nor Mooi *et al.* teach “overexpression.” Mooi *et al.* references PGP9.5 only in Table 2 and on page 334, stating that, “When staining was focal, it was remarkable that NSE positive stands and nodules were generally also PGP 9.5 positive.” The discussion section on pages 335-36 mentions that the examined tumors that were positive for NSE (neurone-specific enolase) were also positive for PGP 9.5. The reference does not teach an “overexpression” of PGP 9.5, only that it correlates with the presence of NSE in the tumors the authors studied. According to the Office, Wilkinson *et al.* teaches expression of PGP9.5 in neurons and ganglia, this combined with Mooi, *et al.* does not establish an “overexpression” of PGP9.5 or its gene. “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by person of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2D 1949, 1950-51 (Fed. Cir. 1999). *See also* MPEP 2112. On the basis for the foregoing, Applicants respectfully request withdrawal of this rejection.

### III. CONCLUSION

No additional fee, other than the fee for the Two Month Extension of time, is deemed necessary in connection with the filing of this Amendment and Response. However, if the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-2518**, referencing billing number **7008712001**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account. Should a telephone advance prosecution of the subject application, the Examiner is invited to contact the undersigned at (650) 849-4950.

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